REMARKS

Objection to the Drawings

The Office Action objects to the drawings. The Office Action states that the first reservoir, the second reservoir, the actuator, and the one-way value must be shown in the drawings.

Applicant notes that the drawings show these features. For example, the drawings depict reservoirs 32, 44, and 46, actuator 50, and one-way check valve 40 in FIGURE 2A.

Accordingly, Applicant respectfully requests the withdrawal of the objection to the drawings.

Rejection under 35 U.S.C. § 112

Claims 18-26 and 49-54 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

The explanation of the rejection under 35 U.S.C. § 112, first paragraph merely states that certain features in the claims are not shown in the drawings. Office Action, page 3. However, as discussed above, the respective features are actually shown in the drawings, namely FIGURE 2A. Moreover, the specification is replete with description how to make and use the invention. *See*, *e.g.*, paragraphs [0032]-[0035].

Accordingly, Applicant requests the Examiner to withdraw the rejection under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 103(a)

Claims 18-26, 49, and 51-54 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,139,397 (hereinafter referred to as "Tucker") in view of U.S. Patent No. 5,700,245 (hereinafter referred to as "Sancoff").

The Office bears the initial burden of factually supporting any prima facie conclusion of obviousness. MPEP § 2142. Additionally, to establish a prima facie case of obviousness, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *See* MPEP § 2142 citing *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

The proffered rejection under 35 U.S.C. § 103(a) does not satisfy these requirements, because the articulated basis underpinning the legal conclusion is factually incorrect.

Claim 18

Claim 18 recites:

> manually applying pressure to a working fluid contained in an actuator associated with an implantable pharmaceutical fluid delivery device, wherein the implantable pharmaceutical fluid delivery device comprises a first fluid reservoir and a second fluid reservoir, thereby causing a flow of the working fluid into the first fluid reservoir;
>
> delivering to the treatment area a first dosage of pharmaceutical fluid from the second fluid reservoir by transferring pressure from the working fluid in the first reservoir to the pharmaceutical fluid in the second reservoir, wherein the working fluid and the pharmaceutical fluid are different fluids; and
>
> delivering to a treatment area a basal flow dosage of the pharmaceutical fluid from a constant flow pump as the first dosage is delivered, the constant flow pump associated with the implantable pharmaceutical fluid delivery device.

The Office Action acknowledges that Tucker "fails to teach the specifics of the bolus delivery."

The Office Action relies on Sancoff to address the "first dosage" limitations as recited in claim 18.

Sancoff is directed to a gas generation structure for an external or "ambulatory" infusion device. That is, the device in Sancoff is adapted to be employed in a similar manner to a conventional "IV stand and bag" device, except that the patient is free to move about. *See* Sancoff, col. 1, lines 20-24 and 52-55 and col. 8, lines 41-44. The delivery of infusate by the device in Sancoff occurs by a controlled reaction of two respective reactants to produce a gas product to drive infusate fluid from a reservoir and into the patient's system. The delivery of the infusate fluid continues until the reactants are consumed by the chemical reaction.

First, it is noted that the infusion in Sancoff is a basal infusion process. That is, the infusion is continuous and does not provide a "bolus" treatment. *See* col. 1, lines 14-21 and col. 5, lines 39-42. Upon this basis alone, one of ordinary skill would not combine or modify the device in Tucker in view of Sancoff to provide a first dosage in additional to a concurrent delivery of basal flow dosage.

Furthermore, the delivery mechanism of Sancoff would not be selected for an implanted infusion device, because such a delivery mechanism is not taught or suggested as being capable of replenishment. That is, the drug delivery in Sancoff occurs in a single use manner, i.e., once the chemical reactions are completed, there is no disclosed manner for "recharging" the reactants. However, implantable drug infusion devices are intended to supply infusate to a patient over a significant amount of time (commonly over months or even years). Thus, one of ordinary skill in the art would not combine or modify the device of Tucker with the single-use mechanism disclosed in Scancoff as proffered in the rejection.

Therefore, the combination of Tucker and Sancoff does not establish a prima facie case of obviousness for claim 18. Claims 19-26 depend from claim 19 and, hence, inherit all limitations of claim 19. A prima facie case of obviousness has not been established for these claims.

Claim 49

Applicant has amended claim 49. The amendment is supported by the original application. No new matter has been entered. Claim 51 is cancelled in view of the amendment to claim 49. The dependencies of claims 52 and 53 have also been changed.

Claim 49 recites:

> providing a temporary bolus infusion rate in response to patient manipulation of an actuator of the implantable infusion drug pump, wherein the bolus infusion rate is provided simultaneously to the basal infusion rate, wherein the providing a temporary bolus infusion rate comprises: (i) driving fluid into a working fluid reservoir by pressure applied by the actuator, the working fluid reservoir and a secondary reservoir being mechanically coupled, the driving of fluid into the working fluid reservoir causing infusate to be drawn from the main reservoir into the secondary reservoir; (ii) providing pressure on infusate in the secondary reservoir to drive the infusate from the secondary reservoir, driving of infusate from the secondary reservoir occurring simultaneously with fluid being driven from the working fluid reservoir toward the actuator; and (iii) controlling a discharge rate from the secondary reservoir to the discharge port using a flow restrictor.

For the reasons discussed above in regard to claim 18, the combination of Tucker and Sancoff does not teach or suggest providing a basal infusion rate and a bolus infusion rate in the manner recited by claim 49.

In further specific regard to claim 49, there is no drawing of infusate from a main reservoir to a secondary reservoir in either of Tucker and Sancoff. Also, in specific regard to claim 49, there is no coupling between the secondary reservoir and a working fluid reservoir in Tucker or Sancoff such that when fluid is driven from the secondary reservoir, fluid is simulataneously driven from the working reservoir toward the actuator.

Therefore, the combination of Tucker and Sancoff does not establish a prima facie case of obviousness for claim 49. Claims 52 and 53 depend from claim 49 and,

hence, inherit all limitations of claim 49. A prima facie case of obviousness has not been established for these claims.

Conclusion

Applicant respectfully submits that the application is in condition for allowance and requests the Examiner to pass the application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge Deposit Account No. 50-3906 from which the undersigned is authorized to draw. Applicant does not believe that an extension of time is necessary. However, if any extension of time is necessary, Applicant hereby petitions for such extension of time and authorizes the Office to charge Deposit Account No. 50-3906 from which the undersigned is authorized to draw for the appropriate extension of time fee.

Respectfully submitted,

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Date: Sept. 2, 2008

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